HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA)
AND HUMAN TISSUE AUTHORITY (HTA)

Regulation of ovarian and testicular tissue

	Scenario 1 **Ovarian or testicular tissue intended for fertility treatment (eg, in vitro maturation of gametes)**	Scenario 2 **Ovarian or testicular tissue intended for autologous (own use) transplantation**	Scenario 3 **Ovarian or testicular tissue, intended future use not certain at time of storage**	Scenario 4 **Ovarian or testicular tissue from a donor or deceased person**
Processing	The Grade C air quality requirements for processing gametes apply (as required by HFEA standard licence condition T20).	The Grade A air quality and other requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 apply. Detailed standards are set out in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.	Processing requirements outlined in Scenario 2 (ie, Grade A air quality) should be applied from the outset if there is a possibility the tissue may be transplanted. Advice should be sought from the HTA on a case-by-case basis, as to whether tissue processed in Grade C air quality can be transplanted.	Contact your HFEA inspector before considering procuring or storing tissue from a donor or deceased person. Where no effective written consent to storage of gametes or tissue has been obtained from the donor/deceased person, their tissue should not be procured (NB. Next of kin cannot consent to donation of ovarian or testicular tissue). If transplant technology develops, to make transplantation of donor tissue possible, mechanisms will need to be put in place to ensure appropriate regulation.
Storage	Storage at an HFEA-licensed centre (HTA licence not required).	Storage at an HTA-licensed centre (HFEA licence not required).	Storage at either an HFEA- or HTA-licensed centre until the intended use of the tissue is determined.	
Use	Derivation and use of gametes must be carried out at an HFEA-licensed centre. The use of gametes extracted from the tissue, and any serious adverse events and reactions are reportable to the HFEA.	Tissue must be processed at an HTA licensed facility before transplantation. The fate of the tissue, and any serious adverse events and reactions are reportable to the HTA.	When the use of the tissue is determined it should be transferred to an appropriately licensed (HFEA or HTA) facility. Tissue cannot be moved directly from an HFEA licensed centre to a transplant unit.	
Distribution	Tissue can be imported or exported if the requirements set out in HFEA General Directions 0006 are fulfilled, or if Special Directions are granted.	Tissue can be distributed within the UK and EU under the terms of an HTA licence.	Tissue to be used for fertility treatment can be imported or exported if the requirements set out in HFEA General Directions 0006 are fulfilled, or if Special Directions are granted. Tissue to be used for transplant can be distributed within the UK and EU under the terms of an HTA licence.	